K102410 (pg 1/2)

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DEC 2 1 2010

5. 510(k) Summary

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, ConMed Linvatec is hereby submitting the 510(k) Summary of Safety and Effectiveness for 510(k) Number _____.

Date Prepared: December 2, 2010

A. Submitter

ConMed Linvatec
11311 Concept Boulevard
Largo, Florida 33773-4908
Registration Number: 1017294

B. Company Contact

Regulatory Contact:
Ashlea Bowen
Regulatory Affairs Specialist
(727) 399-5564 Telephone
(727) 399-5264 Fax

C. Device Name

Trade Name:	Genesys Matryx™
Common Name:	Bioabsorbable Interference Screw
Classification Name:	Biodegradable soft tissues fixation fastener
Proposed Class/Device:	Class II
Product Code:	HWC
Regulation:	21 CFR Part 888.3040

D. Predicate/Legally Marketed Devices

Device Name:	Osteo ACL Screw
Company Name:	Linvatec Biomaterials Ltd.
510(k) #:	K032894
Device Name:	Matryx Interference Screw
Company Name:	Linvatec Biomaterials Ltd.
510(k) #:	K052080
Device Name:	MILAGRO Interference Screw
Company Name:	Depuy Mitek
510(k) #:	K060830

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Device Name:	Bilok Screw
Company Name:	Biocomposites Ltd
510(k) #:	K071091

E. Device Description

The Genesys Matryx is a threaded, cannulated, bioabsorbable interference screw composed of ultra-high strength Self-Reinforced™ (SR) polylactide copolymer and beta-tricalcium phosphate (β-TCP). The Genesys Matryx maintains accurate position of a tendon/ligament graft. The manufacturing process preserves the high initial mechanical strength and stiffness, which allows secure fixation, in combination with appropriate immobilization/controlled mobilization until clinical determination of healing. The Genesys Matryx completes resorption within several years. Resorption also depends on patient variables. The Genesys Matryx need not be removed prior to revision surgery, if such is needed. The Genesys Matryx is sterile and non-collagenous.

F. Intended Use / Indications

The Genesys Matryx™ is for attaching soft tissue to bone in orthopedic surgical procedures. Genesys Matryx™ is intended to be used for interference fixation of soft tissue (including ligaments or tendons) to bone, where the implant sizes offered are patient appropriate. The implant operates in conjunction with appropriate postoperative immobilization, throughout the healing period, to attach soft tissue to bone.

G. Substantial Equivalence

The Genesys Matryx substantially equivalent in design, manufacturing materials, intended use, principles of operation, and technical characteristics to the Linvatec Biomaterials Ltd Osteo ACL Screw (K032894), the Linvatec Biomaterials Matryx Interference Screw (K052080), the Depuy Metik MILAGRO Interference Screw (K060830), and the Biocomposites Ltd. Bilok Screw (K071091).

H. Non-Clinical Testing

Non-clinical testing was submitted to aid in the characterization of the Genesys Matryx device and to support a determination of substantial equivalence. This testing included in vivo animal testing, in vitro degradation, shelf life, transportation and distribution, verification by analysis, insertion, pullout, cyclic (reliability) and bioburden testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ConMed Linvatec
% Ms. Ashlea Brown
Regulatory Affairs Specialist
11311 Concept Boulevard
Largo, Florida 33773

DEC 2 1 2010

Re: K102410
Trade/Device Name: Genesys Matryx™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: December 1, 2010
Received: December 2, 2010

Dear Ms. Brown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4. Indications for Use

DEC 2 1 2010

510(k) Number (if known): K102410 (pg 1/1)

Device Name: Genesys Matryx™

Indications for Use:

The Genesys Matryx™ is for attaching soft tissue to bone in orthopedic surgical procedures. Genesys Matryx™ is intended to be used for interference fixation of soft tissue (including ligaments or tendons) to bone, where the implant sizes offered are patient appropriate. The implant operates in conjunction with appropriate postoperative immobilization, throughout the healing period, to attach soft tissue to bone.

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Mckenna

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102410